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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/633,034	08/04/00	TSANG K	A33081

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HM22/0627

EXAMINER	
WELLS, M	
ART UNIT	**PAPER NUMBER**
1642	2

DATE MAILED: 06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/633,034	Applicant(s) TSANG ET AL.	
	Examiner Matthew O. Wells	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, and 6-15, drawn to a monoclonal antibody, 33.28, specific for human colon carcinoma associated antigen having a molecular weight of about 61.1 kilodaltons, classified in class 530, subclass 388.85.

II. Claims 1, 4-5, and 7-15, drawn to a monoclonal antibody, 31.1, specific for human colon carcinoma associated antigen having a molecular weight of about 72 kilodaltons, classified in class 530, subclass 388.85.

III. Claims 16-18, and 21, drawn to a monoclonal antibody against the monoclonal antibody 33.28, classified in class 530, subclass 388.1.

IV. Claims 16, and 19-20, drawn to a monoclonal antibody against the monoclonal antibody 31.1, classified in class 530, subclass 388.1.

V. Claim 22, drawn to an immunoassay using the monoclonal antibody 33.28, classified in class 435, subclass 7.1.

VI. Claim 23, drawn to an immunoassay using the monoclonal antibody 31.1, classified in class 435, subclass 7.1.

VII. Claims 24, 26, 29, and 48, drawn to a histological kit and method for diagnosing colon cancer in humans using the monoclonal antibody 33.28, classified in class 435, subclass 40.52.

VIII. Claims 25, 27, 28, and 48, drawn to a histological kit and method for diagnosing colon cancer in humans using the monoclonal antibody 31.1, classified in class 435, subclass 40.52.

IX. Claims 30-37, drawn to compartmentalized kits comprising the monoclonal antibody 31.1, classified in class 435, subclass 7.1.

X. Claims 38-41, drawn to compartmentalized kits comprising the monoclonal antibody 33.28, classified in class 435, subclass 7.1.

XI. Claims 1, and 42-45, drawn to the chimeric monoclonal antibody, classified in class 530, subclass 387.3.

XII. Claim 46, drawn to a monoclonal antibody against the chimeric antibody of group XI, classified in class 530, subclass 388.1.

XIII. Claim 47, drawn to an immunassay using the chimeric antibody Chi #1, classified in class 435, subclass 7.1.

XIV. Claims 49-50, drawn to a histological kit and the method of using Chi #1 to diagnose colon cancer in humans, classified in class 435, subclass 40.5.

2. The inventions are distinct, each from the other because of the following reasons:

a. The products of Groups I-IV, XI-XII are distinct as the products have different structures, different immunological properties, and are used for different purposes.

b. The methods of Groups V-X and XIII-XIV are distinct as the methods use structurally different products.

c. Inventions I and V, VII, and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the monoclonal antibody can be used in the materially different process of affinity purification of polypeptides.

d. Inventions II and VI, VIII, and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the monoclonal antibody can be used in the materially different process of affinity purification or polypeptide purification.

e. Inventions XI and XIII-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the chimeric antibody of group XI can be used in affinity purification of proteins.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and/or require different search strategies, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

6. Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew O. Wells whose telephone number is 703-308-4521. The examiner can normally be reached on M-F (7:00-4:30), every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Matthew Wells
June 12, 2001

Brenda Brumback
BRENDA BRUMBACK
PATENT EXAMINER